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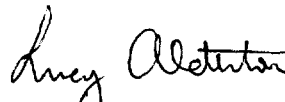
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: **Food Code Prohibition Against Bare Hand Contact With Ready-to-Eat  
Foods; Preparation of a White Paper for Review by the National Advisory  
Committee on Microbiological Criteria for Foods**  
**Docket No. 99N-0438**  
**64 Fed.Reg. 15978 (April 2, 1999)**  
**Addendum**

Dear Dockets Manager:

An attachment was inadvertently left out of the Center for Science in the Public Interest's (CSPI) June 1, 1999, comments on the above *Federal Register* notice. Please add the enclosed study: Eric D. Mintz, et al., "Foodborne Giardiasis in a Corporate Office Setting," *Journal of Infectious Diseases*, Vol. 167 (1993), pp. 250-253, to Appendix A, "Foodborne-Illness Outbreaks Associated with Infected Food-Preparation Workers," of CSPI's comments.

Sincerely,



Lucy Alderton  
Project Coordinator  
Food Safety

99N-0438

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## Foodborne Giardiasis in a Corporate Office Setting

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Giardiasis is the most commonly reported intestinal protozoal infection worldwide, but its relatively long incubation period and often insidious onset make detection of common-source outbreaks difficult. Few well-documented foodborne outbreaks of giardiasis have been reported. In November 1990, such an outbreak among insurance company employees resulted in 18 laboratory-confirmed and 9 suspected cases of giardiasis. A case-control study of 26 ill and 162 well employees implicated raw sliced vegetables served in the employee cafeteria and prepared by a food handler infected with *Giardia lamblia* as the probable vehicle (odds ratio, 5.1; 95% confidence interval, 1.4–22.7). This outbreak illustrates the potential for transmission of *Giardia* organisms to occur in commercial establishments through a frequently served food item.

Infection with *Giardia lamblia*, the most common parasitic cause of diarrhea, may be acquired through person-to-person transmission or ingestion of fecally contaminated water or food [1]. However, the long incubation period, insidious onset, and variable symptoms of giardiasis make detection of foodborne outbreaks difficult. Foodborne transmission has previously been documented among attendees of special events where food was prepared and served by non-professional food handlers [2–4] and among residents and staff of a nursing home [5]. In a recent report, ice contaminated by an infected food handler was implicated as the probable vehicle in a restaurant-associated giardiasis outbreak [6]. This report describes a foodborne giardiasis outbreak associated with a company cafeteria.

### Background

The corporate campus of insurance company A has two office buildings; 3500 employees work in the main building and 1175 in the annex. The employee cafeteria in each building is operated by a private contractor. Employees may eat in either cafeteria, but they generally eat in the building where they work. Water is supplied to both buildings from a common public source.

On 20 December 1990, a company physician reported 4 confirmed cases and 1 suspected case of giardiasis among employees. All 5 case-patients worked in the annex building and had onset of gastrointestinal symptoms in early No-

vember 1990. Case-patients were interviewed regarding symptoms, food and water consumption, travel, outdoor activities, contact with day care attendees, and coworkers with a similar illness. Nine coworkers reported to be ill were interviewed and tested for giardiasis; 8 were excreting *Giardia* cysts. Food, water, and ice served in the annex building were the only exposures common to all case-patients.

### Methods

**Subjects.** On 16 January, a notice was posted on campus bulletin boards asking all employees with diarrhea or abdominal cramps lasting  $\geq 5$  days or with a diagnosis of giardiasis since 1 October to come to Employee Health Services for interviews. Employees who had not previously been evaluated for giardiasis were requested to submit a single stool specimen if they had diarrhea or abdominal cramps lasting  $< 5$  days since 1 October and 3 specimens if the diarrhea or cramps lasted  $\geq 5$  days.

On 31 December, food preparation and serving facilities in the annex employee cafeteria were inspected, and all 35 cafeteria employees were interviewed regarding symptoms and food-handling practices. Between 11 and 18 January, stool specimens were collected from the 19 cafeteria employees who prepared or served food in October 1990.

**Treatment of specimens.** Stool specimens were collected in 10% formalin and in polyvinyl alcohol fixative. Formalin-preserved specimens were examined for *G. lamblia* cysts after ethyl acetate concentration and staining with Dobel's iodine stain [7]. Smears prepared from specimens in polyvinyl alcohol were examined for trophozoites after trichrome staining. ELISA with the ProSpecT/Giardia kit (Alexon, Mountain View, CA) was done on 1 stool specimen from each interviewed employee and food handler with negative microscopic examinations.

In January, water treatment records were reviewed and the annex water distribution system was inspected. From 24 December through 6 February, water samples were systematically collected from the annex building and tested for total and fecal coliforms.

**Risk factor study.** A case-control design was selected to evaluate risk factors for illness among annex building employees. Employees with onset of diarrhea between 1 October and 1 De-

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cember 1990 were considered to have confirmed cases if a stool specimen contained *Giardia* and considered to have suspected cases if they reported diarrhea lasting  $\geq 5$  days in the absence of a positive stool specimen. Employees whose names were listed after the names of each case-patient in the alphabetized employee roster were selected as controls. Twelve controls were selected for each case to obtain a 1:5 case-to-control ratio given an expected response rate of 40%–50% among well employees. To be eligible, controls had to have been employed in the annex building in October, have missed  $\leq 7$  work days during that month, and have denied having diarrhea since 1 October.

On 11 February, study participants were sent questionnaires regarding onset and duration of gastrointestinal symptoms between 1 October and 1 December 1990, related physician visits, and attendance at catered events in October. The number of times per week that specific food items from the annex employee cafeteria were consumed in October and the sources and quantity of water and ice consumed in the annex building were also requested. Odds ratios (ORs) and their exact 95% confidence intervals (CIs) were calculated.

## Results

From 16 January through 1 March, 112 employees responded to the notice posted by Employee Health Services. Fifty (47%) reported diarrhea or severe abdominal cramps with onset after 1 October; of these, 42 submitted  $\geq 1$  stool specimens within 2 weeks of the interview. Overall, 18 confirmed cases and 9 suspected cases were identified. One person with a suspected case declined further participation, for a total of 26 cases. No additional cases were found through ELISA of stool specimens from employees with negative microscopic examinations.

For the 26 cases, the median duration of diarrhea was 35 days (mean, 37; range 1–90). In addition to having diarrhea, most case-patients reported increased flatulence (96%), foul-smelling stools (77%), increased fatigue (73%), cramps (69%), nausea (65%), and weight loss (65%). Eighteen case-patients (69%) consulted a physician. A diagnosis of giardiasis was made in 10 of 12 case-patients who saw physicians before learning of the outbreak.

The dates of diarrheal onset are shown by week in figure 1. Of the 26 case-patients, 20 became ill between 28 October and 10 November, suggesting exposure in late October and early November. Exposures to recognized risk factors for *Giardia* were uncommon; in the month before onset of symptoms, only 6 case-patients (23%) reported contact with a child  $\leq 5$  years old, and only 2 (8%) reported drinking untreated water.

Completed questionnaires were returned within 4 weeks by all 26 case-patients and 235 (70%) of 336 controls. After exclusion of 12 controls who missed  $\geq 7$  work days in October, 27 who reported diarrhea, and 21 who did not deny diarrhea since 1 October, 175 remained.

The risk of illness did not differ by office location, water and ice consumption, or attendance at catered events.

All 26 case-patients and 162 controls (93%) reported eat-

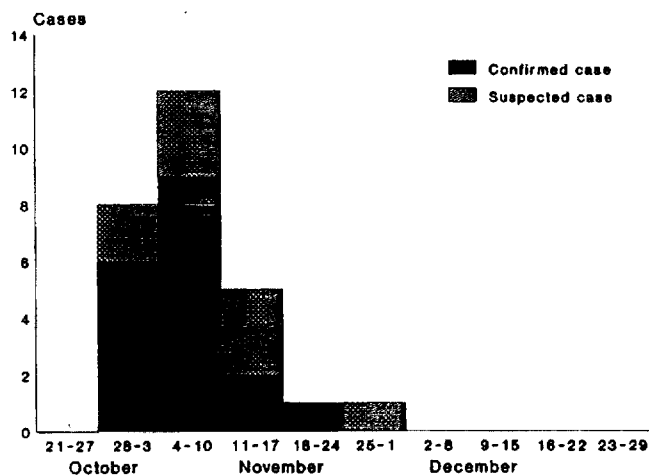


Figure 1. Giardiasis in Company A employees: cases by week of onset, 1990.

ing food from the annex employee cafeteria one or more times a week during October. Estimated food-specific risks of illness were calculated for these employees (table 1). Two food items substantially increased the risk of illness: sliced raw vegetables from the salad bar and yogurt. Sliced raw vegetables, eaten by 88% of case-patients (94% of confirmed cases) and 60% of controls, had the strongest association with illness (OR, 5.1; CI, 1.4–27.6). Only 60% of case-patients (61% of confirmed cases) reported eating yogurt (OR, 2.9; CI, 1.1–7.7). Limiting the analysis to confirmed cases strengthened the association between sliced raw vegetables and illness (OR, 11.3; CI, 1.7–481); in logistic regression, only this association remained significant. Two other salad bar items also had elevated ORs: leafy green vegetables (OR, 3.1) and cold meats and cheeses (OR, 2.8); however, CIs for these items included 1.0.

No deficiencies were evident on review of water treatment records or environmental inspection of the water distribution system. No coliforms were detected in the 55 tested water samples.

Inspections of food preparation and serving facilities in the annex building revealed no deficiencies. All food handlers denied diarrhea or abdominal cramps lasting  $\geq 2$  days in the 3 months before the interview.

*Giardia* cysts were identified in the stool specimen of only 1 of the 19 food handlers. This person prepared sliced raw vegetables and cold meats and cheeses for the salad bar and a shredded carrot garnish for the cole slaw and she served sandwiches from December 1988 until her stool specimen was reported positive on 21 January 1991. She denied any gastrointestinal symptoms in the previous 6 months or any prior history of giardiasis. She had not left the United States since 1987 and denied contact with day care attendees, pets, or untreated water. She always wore gloves when serving sandwiches but was observed preparing vegetables for the

**Table 1.** Food histories and estimated risks of illness, giardiasis outbreak, corporate office setting, 1990.

	% exposed		OR	95% CI
	Cases (n = 26)	Controls (n = 162)		
Salad bar				
Leafy greens	85	64	3.1	0.9-11.3
Prepared salads	64	45	2.2	0.8-5.9
Sliced raw vegetables	88	60	5.1	1.4-22.7
Meats and cheeses	73	49	2.8	1.0-8.1
Cold plates	12	13	0.9	0.2-3.8
Desserts				
Sliced fruit	56	38	1.8	0.7-4.7
Hot dessert	23	14	1.8	0.6-5.5
Yogurt	60	34	2.9	1.1-7.7
Ice cream	42	23	2.4	0.9-6.4
Cold dessert	19	23	0.8	0.2-2.5
Whole fruit	24	30	0.7	0.2-2.1
Hot foods				
Entree	68	65	1.2	0.4-3.2
Grilled items	52	53	1.0	0.4-2.5
Soup	73	75	0.9	0.3-2.6
Bread	42	41	1.1	0.4-2.7
Sandwich bar				
Deli sandwich	67	63	1.2	0.4-3.2
Wrapped sandwich	9	15	0.5	0.1-2.6
Carvery sandwich	64	47	2.0	0.8-5.3
Side orders				
Lettuce	72	66	1.3	0.5-3.7
Tomato	62	56	1.3	0.5-3.3
Cheese	65	50	1.9	0.7-4.9
Cole slaw	54	36	2.1	0.8-5.3

NOTE. OR, odds ratio; CI, confidence interval.

salad bar without gloves. Her husband, who also denied risk factors for giardiasis, had complained of increased cramping and irritated bowels since mid-November. On 24 January, he submitted a stool specimen that contained *Giardia* cysts.

## Discussion

In this outbreak, epidemiologic and laboratory evidence implicated an asymptomatic food handler as the probable source and raw sliced vegetables as the vehicle of *G. lamblia* transmission in a novel setting—a commercial cafeteria in a corporate office building. No evidence was found to support waterborne transmission, a documented source of many other giardiasis outbreaks.

The date and means by which the food handler acquired giardiasis are unknown, but the outbreak appears to have been self-limited, with peak transmission in late October and early November. Although the food handler was still excreting *Giardia* cysts on 16 January, only 2 employees with confirmed cases had onset of diarrhea after 1 December.

There are three possible explanations for the apparent temporal clustering of cases. The food handler may have been more infectious earlier in the course of her infection and may have excreted fewer cysts as the infection progressed. Alternatively, she may have committed more frequent or serious breaches of food-handling techniques on specific occasions in late October and early November. A more remote possibility is that a single contaminated lot of raw vegetables purchased and consumed during this period was the source of infection for the 26 company employees and for the food handler.

Case histories suggest that more than one meal was contaminated. Confirmed cases include 1 employee who ate in the annex only on 4 and 16 October and had symptom onset on 4 November and 3 others who were absent from work on 16 October. The 4 October meal would require incubation periods of 4-8 weeks to explain the onset dates of all confirmed cases. This would be highly unusual, given that the typical incubation period for giardiasis is 1-2 weeks [8].

The total number of persons infected with *Giardia* as a result of this outbreak was not determined but was probably greater than the 27 cases identified through passive surveillance. Routine collection of stool specimens from employees with diarrhea or cramps began several weeks after the probable exposure period, and it is likely that some infected persons were no longer excreting *Giardia* cysts or antigen at the time specimens were collected. Although 27 persons in the control group (11%) reported diarrhea between 1 October and 31 December and 8 (3%) reported diarrhea lasting  $\geq 5$  days, they were excluded from the study without an evaluation for *Giardia* infection. Asymptomatic cases usually represent 50%-75% of infected persons [8], but no attempt was made to collect stool specimens from employees who did not report diarrhea or severe abdominal cramps. Although some asymptomatic infected persons may have been included among controls, the resulting misclassification would bias against finding an association and does not alter the study conclusions.

The implicated vehicles in four previously reported food-borne outbreaks of giardiasis were cold foods (salmon and cream cheese dip, noodle salad, sandwiches, and fruit salad). Only one additional outbreak of giardiasis, for which a specific vehicle was not identified, was noted in national food-borne outbreak surveillance conducted by the Centers for Disease Control from 1973 through 1988. In three of the reported outbreaks, food was contaminated during preparation or service by nonprofessional food handlers [2-4]; the fourth occurred in a nursing home where 8 of 14 sandwich preparers had laboratory-confirmed giardiasis [5].

Commercial salad bars offering raw vegetables and other cold foods whose preparation requires extensive handling have become increasingly popular. This outbreak suggests that giardiasis may be transmitted through a food item served in many commercial establishments and many homes. It was

detected because most cafeteria diners were company employees whose medical care was the responsibility of a single health-management team. Had the infected food handler worked in an establishment serving a different clientele, the outbreak might not have come to the attention of medical and public health workers. Investigators should consider foodborne transmission and obtain stool specimens to detect ova and parasites from food handlers whenever a meal or food service establishment is implicated in an outbreak of giardiasis. Proper food-handling measures, including hand washing, washing vegetables, and using gloves and clean utensils in preparing raw vegetables and other cold foods, may help prevent foodborne transmission of *G. lamblia*.

#### Acknowledgments

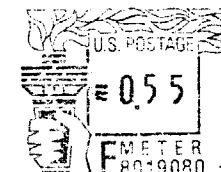
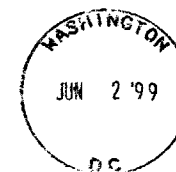
We thank Henry Mathews for doing the ELISAs for *Giardia*-specific antigen and David Addiss for reviewing the manuscript.

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